UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

MDL No. 2875

Honorable Robert B. Kugler, District Court Judge

This Document Relates to All Actions

Honorable Joel Schneider, Magistrate Judge

COMPENDIUM OF CHARTS REFERENCED IN THE MANUFACTURER DEFENDANTS' REPLY BRIEF

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NEW ALLEGED FACTS AND EXTRINSIC MATERIALS

New Facts Alleged in Plaintiffs' Opposition	Opposition Page Number	External Source Cited
"The API is the part of any drug that produces the intended effects. The excipient is any substance other than the API that helps deliver the medication to the human body system. While in certain specific instances generic manufacturers may use different excipients in the formulation of their generic drugs (provided they do not affect bioequivalence), the API must be the same."	8-9	None
"Prior to submitting an ANDA, a generic drug manufacturer may submit a Drug Master File ("DMF") to the FDA. DMFs are submissions to the FDA used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of the API which make up all prescription drugs. Unlike ANDAs, DMFs are neither approved nor disapproved. Rather, the FDA simply reviews the technical contents of the DMF when the agency ultimately receives, reviews, and decides on whether to approve an ANDA."	9	None
"Nitrosamines are known human carcinogens. Their only commercial purpose is to induce cancer in laboratory mice."	9	None
"At present, all Repackager/Relabeler Defendants save one (which has not moved to dismiss) have availed themselves of the court- approved process for the dismissal without prejudice of certain defendants."	10-11	None

New Facts Alleged in Plaintiffs' Opposition	Opposition Page Number	External Source Cited
"To illustrate the above in more detail, ZHP, as both a valsartan API and finished-dose manufacturer, originally developed a four-step process for the manufacture of valsartan API."	13	Letter Brief at ECF 296, 3-4
"To facilitate the chemical reaction necessary to form the specific tetrazole ring structure in these sartans, Process I utilized multiple chemical agents including tributyl tin chloride."	13	Letter Brief at ECF 296, 3-4
"This agent was the same one used by Novartis to manufacture the valsartan API in its branded Diovan and Exforge products, as publicly disclosed in Novartis's NDA on file with the FDA. However, this process was disfavored by ZHP for a host of reasons, the chief of which was cost."	13-14	Letter Brief at ECF 296, 4-5
"ZHP could not yet sell its generic valsartan in the United States because of Novartis's patent protection until at least 2012, but ZHP could and did begin selling generic valsartan in other countries."	14	Letter Brief at ECF 296, 4-7
"ZHP's first manufacturing process was expensive. To cut costs, ZHP devised a second process – Process II – which substituted a different, cheaper chemical agent – triethylamine hydrochloride ("TEA") – in step 4 in lieu of tributyl tin chloride."	14	Letter Brief at ECF 296, 5
"Process II also replaced the solvent used in Process I (xylene) with a different solvent (toluene). Toluene is a cheaper, yet more volatile solvent agent. Nevertheless, replacing Process I with Process II yielded ZHP's intended result – the substitution of cheaper chemical agents reduced ZHP's costs and	14	Letter Brief at ECF 296, 5

New Facts Alleged in Plaintiffs' Opposition	Opposition Page Number	External Source Cited
increased its profits for overseas valsartan sales."		
"Setting the stage for its profits-driven process-switch abroad, in January 2010 ZHP (through its United States subsidiaries), filed a second DMF with the FDA. This new DMF listed the same process change – Process I to Process II – that ZHP implemented for its non-United States valsartan."	14	Letter Brief at ECF 296, 29
"In its submission, ZHP explicitly acknowledged that switching from tributyl tin chloride to cheaper triethylmaine hydrochloride reduced the "economic cost" to make valsartan API."	14	Letter Brief at ECF 296, 29
"What ZHP did not admit was that its decision to cut costs to pursue greater profits resulted in carcinogenic contamination of its valsartan API made pursuant to Process II."	14	None
"The scientific literature reported that the chemical reactions to form desired chemical compounds could lead to the unwanted creation of nitrosamines as well."	19	"scientific literature"
"Discovery has already revealed the existence of express warranties made by manufacturers to wholesalers/retailers, which contain express warranties made for the benefit of consumers as intended third party beneficiaries."	62, footnote 16	Discovery
"Those agreements exist between all of the Retailer Pharmacy Defendants and Manufacturers or Wholesalers in this case Some of these indemnification agreements have	67, footnote 21	Discovery

New Facts Alleged in Plaintiffs' Opposition	Opposition Page Number	External Source Cited
already been produced in discovery, and many of them have been improperly redacted."		
"Indeed, from 2016 to 2018, 22 batches of API were rejected and/or returned by customers because they failed to meet specifications and/or were presenting with aberrant testing."	80, footnote 42	Letter Brief at ECF 296, 5
"From January 22, 2016 to June 29, 2017 alone, there were 17 out-of-specification ("OOS") investigations regarding one particular batch of valsartan API These investigations were never successfully resolved This batch, it would later turn out, had been contaminated with genotoxic impurity the entire time."	80, footnote 42	Letter Brief at ECF 296, 29
"When confronted with these rejected, refused, an/or [sic] OOS batches, instead of conducting a root cause analysis, ZHP simply re-processed the raw material and sold it to other customers."	80, footnote 42	Letter Brief at ECF 296, 27-28
"Plaintiffs have adequately pleaded that Defendants knew or should have known that their nitrosamine-contaminated Valsartan could cause cancer in humans, and failed to warn of these risks. Discovery has yielded illustrative evidence on this point."	91	Discovery; Letter Brief at ECF 296, 4-7
"When asked why it made this change, ZHP's Executive Vice President Jun Du suggested it was to save money [sic] increase market share."	96	Letter Brief at ECF 296, 4-5
"Even more egregiously, ZHP instituted this manufacturing change at a commercial scale in spite of its developer's direction that the synthesis and purification process including the solvent system had to be further refined at the testing scale These facts lead to one	97	Letter Brief at ECF 296, 4-5

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New Facts Alleged in Plaintiffs' Opposition	Opposition Page Number	External Source Cited
reasonable conclusion: ZHP wantonly and willfully manufactured its valsartan using an unoptimized purification process that failed to detect highly potent genotoxic impurities, such as NDMA or NDEA, so that it could increase its profits and market share."		
Pre-litigation letters purportedly sent to certain Defendants.	Exhibit 1	Purported Pre- Litigation Letters

NON-EXHAUSTIVE LIST OF STATES REQUIRING LOSS OF FUNCTIONALITY OR PHYSICAL HARM FOR BREACH OF IMPLIED WARRANTY

State	Authority
Alabama	Bodie v. Purdue Pharma Co., 236 F. App'x. 511, 524 (11th Cir. 2007) (unpublished) (The drug OxyContin did not breach implied warranty of merchantability where it "managed [Plaintiff's] pain and improved his quality of life" even if it was allegedly "unsafe" and "dangerous."); In re Trasylol Prods. Liab. Litig., No. 08–MD–01928, 2010 WL 5140439, at *13 (S.D. Fla. Feb. 16, 2010) (applying Alabama law) (holding that allegations that a drug was unsafe could not support breach of implied warranty where plaintiff did not also "argue that Trasylol was not fit for its intended use in reducing perioperative bleeding in patients undergoing cardiac surgery[.]")
California	Tietsworth v. Sears, 720 F. Supp. 2d 1123, 1142–43 (N.D. Cal. 2010) ("However, her allegations of continued use of the Machine throughout the one-year warranty period belie her claim that it failed to serve its ordinary purpose.")
Illinois	Baldwin v. Star Sci., Inc., 78 F. Supp. 3d 724, 741 (N.D. III. 2015) ("Plaintiff does not allege in what way the product was ineffective.")
Minnesota	O'Neil v. Simplicity, Inc., 553 F. Supp. 2d 1110, 1115 (D. Minn. 2008) ("It is simply not enough for a plaintiff to allege that a product defect suffered by others renders that same product unsafe; the plaintiff must instead allege an actual manifestation of the defect that results in some injury in order to state a cognizable claim for breach of warranty[.]") (emphasis in text)
New York	Caronia v. Philip Morris USA, Inc., 715 F.3d 417, 421, 434 (2d Cir. 2013) ("[W]hether Philip Morris could have made Marlboro cigarettes safer, therefore, is not an issue that is material to the claim of breach of implied warranty of

	merchantability[,]" despite plaintiffs' allegation that manufacturer used tobacco "known to contain high levels of cancer-causing nitrosamines[.]")
Oklahoma	Harrison v. Leviton Mfg. Co., Inc., No. 05-0491, 2006 WL 2990524, at *6 (N.D. Okla. Oct. 19, 2006) ("Courts do not allow consumers to bring claims against manufacturers for products that are perceived to be harmful, but that have not actually cause an identifiable injury A necessary part of every breach of warranty claim is that plaintiff suffer an actual loss that was proximately caused by defendant's breach of warranty[.]")
Pennsylvania	Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364, 379–80 (D.N.J. 2004) (applying Pennsylvania law) ("These plaintiffs would be hard pressed to claim that they did not get what they paid for. Indeed, the record unequivocally establishes that Celebrex and Vioxx were effective treatments for arthritis pain[.]")
Texas	Gen. Motors Corp. v. Brewer, 966 S.W.2d 56, 57 (Tex. 1998) (quoting Plas–Tex, Inc. v. U.S. Steel Corp., 772 S.W.2d 442, 443–44 (Tex. 1989) ("For goods to breach [the implied warranty of merchantability], they must be defective—that is, they must be 'unfit for the ordinary purposes for which they are used because of a lack of something necessary for adequacy.")
West Virginia	Emp. Teamsters-Local Nos. 175/505 Health and Welfare Trust Fund v. Bristol Myers Squibb Co., 969 F. Supp. 2d 463, 470 (S.D.W. Va. 2013) ("Plaintiffs do not allege that Plavix was not fit for its ordinary purpose of being an anticoagulant.")

STATES REQUIRING RELIANCE ON OR KNOWLEDGE OF A WARRANTY FOR IT TO FORM THE "BASIS OF THE BARGAIN"

State	Reliance on Warranty	At Least Knowledge of Warranty
Arkansas	Ciba-Geigy Corp. v. Alter, 834 S.W.2d 136, 146–47 (Ark. 1992) ("When a buyer is not influenced by the statement in making his or her purchase, the statement is not a basis of the bargain."); see also Brooks v. Remington Arms Co., No. 09-01054, 2010 WL 6971894, at *5 (W.D. Ark. Oct. 27, 2010) ("[T]he Arkansas Supreme Court directly addressed this issue and held that reliance is an essential element of an express warranty claim[.]")	
California		Tae Hee Lee v. Toyota Motor Sales U.S.A., Inc., 992 F. Supp. 2d 962, 979 (C.D. Cal. 2014) (Plaintiffs do not allege that they read or relied on the 'marketing brochure' before making their purchases."); In re Toyota, 754 F.Supp.2d 1145, 1182 (C. D. Cal. 2010) ("California law does not permit Plaintiffs, in the absence of specific allegations that they were aware of the statements made in a national advertising campaign, to base their express warranty claims on

State	Reliance on Warranty	At Least Knowledge of Warranty
		statements made in that national advertising campaign.")
Colorado	Assocs. of San Lazaro v. San Lazaro Park Props., 864 P.2d 111, 115 (Colo. 1993) ("Sellers are encouraged to warrant only that which they know they can fulfill, while buyers who in fact rely on express warranties may anticipate judicial enforcement thereof.")	
Connecticut	Web Press Serv. Corp. v. New London Motors, 525 A.2d 57, 67 (Conn. 1987) ("Under the common law action, and under several of the warranty provisions of the code a plaintiff still must prove reliance and that the representation became part of the basis of the bargain."); Danise v. Safety-Kleen Corp., 17 F. Supp. 2d 87, 97 (D. Conn. 1998)	
Delaware	Dilenno v. Libbey Glass Div., Owens–Ill., Inc., 668 F. Supp. 373, 376 (D. Del. 1987) ("It is clear that a successful action for breach of an expressed warranty may not be maintained in Delaware absent	

State	Reliance on Warranty	At Least Knowledge of Warranty
	some reliance by the buyer on the warranty.")	
Florida	Thursby v. Reynolds Metals Co., 466 So.2d 245, 250 (Fla. Dist. Ct. App. 1984) ("[A]n express warranty is generally considered to arise only where the seller asserts a fact of which the buyer is ignorant prior to the beginning of the transaction and on which the buyer justifiably relies as part of the 'basis of the bargain.'"); see also Royal Typewriter Co. v. Xerographic Supplies Corp., 719 F.2d 1092, 1101 (11th Cir. 1983) ("[A]bsence of reliance will negate the existence of an express warranty."); In re Hardieplank Fiber Cement Siding Litig., 284 F. Supp. 3d 918, 943–44 (D. Minn. 2018) (applying Florida law) (finding that regardless of whether reliance is required, the representation must be heard or seen)	
Georgia		Am. Coach Lines of Orlando, Inc. v. N. Am. Bus Indus., Inc., No. 09-1999, 2011 WL 653524, at *16 (M.D. Fla. Feb. 14, 2011) (applying Georgia law) ("[B]ecause all statements were made

State	Reliance on Warranty	At Least Knowledge of Warranty
		after the buses were delivered to American Coach NABI's statements to American Coach were not part of the 'basis of the bargain'"); In re Hardieplank Fiber Cement Siding Litig., 284 F. Supp. 3d 918, 933 (D. Minn. 2018) (applying Georgia law) (finding marketing materials were not basis of bargain because Plaintiff was "never exposed" to those materials "before" he made a purchase)
Hawaii		Torres v. Nw. Eng'g Co., 949 P.2d 1004, 1015 (Haw. 1997) ("[A] plaintiff claiming a breach of express warranty based on an advertisement contained in a catalogue or brochure would normally have to prove, at a minimum, that he or she read, or at least was aware of, the catalogue or brochure.")
Illinois	In re Nexus 6P Prod. Liab. Litig., 293 F. Supp. 3d 888, 917 (N.D. Cal. 2018) (applying Illinois law) ("When privity is lacking, the background rule mandates pleading and proving reliance."); Coryell v. Lombard Lincoln–Mercury	

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	Merkur, Inc., 544 N.E.2d 1154, 1158 (Ill. App. Ct. 1989) (requiring reliance for express warranty)	
Iowa	Sharp v. Tamko Roofing Prods., Inc., No. 02-0728, 695 N.W.2d 43, 2004 WL 2579638, at *2 (Iowa Ct. App. Nov. 15, 2004) (unpublished opinion) ("[P]laintiffs have failed to present a genuine issue of material fact to show they relied on the statements For a plaintiff to prove a breach of an express warranty based on sales representations, there must be a finding the sale would not have been made but for the representations."); Nationwide Agribusiness Ins. Co. v. SMA Elevator Const. Inc., 816 F. Supp. 2d 631, 686 (N.D. Iowa 2011) ("There is authority for the proposition that advertising materials can be the basis for an express warranty, but only if the other elements of the claim, including reliance, are met.").	
Kansas		Voelkel v. Gen. Motors Corp., 846 F. Supp. 1482, 1485 (D. Kan. 1994) ("There is no evidence that [the plaintiff] read or knew of the 1984 sales manual in May of 1990

State	Reliance on Warranty	At Least Knowledge of Warranty
		prior to purchasing the 1984 [car] from a non-GMC used car dealer."); Brand v. Mazda Motor Corp., 978 F. Supp. 1382, 1390 (D. Kan. 1997) (noting requirement that buyer must know of a representation prior to purchase for it to become part of the basis of the bargain)
Kentucky	Overstreet v. Norden Lab., 669 F.2d 1286, 1291 (6th Cir. 1982) (applying Kentucky law) ("A warranty is the basis of the bargain if it has been relied upon as one of the inducements for purchasing the product.")	
Maine	Phillips v. Ripley & Fletcher Co., 541 A.2d 946, 950 (Me. 1988) ("[T]he purchaser must show reliance on the affirmation in order to make out a cause of action for breach of warranty.")	
Maryland		Morris v. Biomet, Inc., No. 18-2440, 2020 WL 5849482, at *12 (D. Md. Sept. 30, 2020) ("Here, there is no evidence from which a jury could determine Plaintiff ever saw any express warranty from Biomet that the product was 'pain-free."")

State	Reliance on Warranty	At Least Knowledge of Warranty
Massachusetts	Sebago, Inc. v. Beazer E., Inc., 18 F. Supp. 2d 70, 102 (D. Mass. 1998) ("[T]he plaintiff must demonstrate that the buyer relied on the warranty."). Stuto v. Corning Glass Works, No. 88-1150, 1990 WL 105615, at *6 (D. Mass. July 23, 1990) ("[P]laintiff could not have relied on the express warranty [because] [s]he cannot recall having ever seen or heard advertisements prior to litigation[.]")	
Michigan	Monte v. Toyota Motor Corp., Nos. 220671, 220983, 2001 WL 1152901, at *3 (Mich. Ct. App. Sept. 28, 2001) ("[P]laintiff could not have relied on any of the statements included in either the Owner's Manuel or Owner's Guide considering that he received both after the bargain was already struck.") (emphasis in original), appeal denied, 651 N.W.2d 912 (Mich. 2002) (unpublished); Dow Corning Corp. v. Weather Shield Mfg., Inc., 790 F. Supp. 2d 604, 611 (E. D. Mich. 2011) ("[A]dvertisements and promotional literature can be a part of the basis of the bargain and thus constitute express	

State	Reliance on Warranty	At Least Knowledge of Warranty
	warranty where they are prepared and furnished by a seller to induce purchase of its products and the buyer relies on the representations.")	
Minnesota	Hendricks v. Callahan, 972 F.2d 190, 193–94 (8th Cir. 1992) ("[W]e are not convinced Minnesota has completely abandoned the requirement of reliance.")	
Mississippi	Global Truck & Equip. Co. v. Palmer Mach. Works, Inc., 628 F. Supp. 641, 651–52 (N. D. Miss. 1986) ("[P]laintiff failed to prove by a preponderance of the evidence that the statements contained in the Palmer brochure were relied upon by Randall prior to or contemporaneously with the making of the contract between Global and Palmer."); Craig v. DaimlerChrysler Corp., No. 06-450, 2008 WL 2816842, at *7 (S.D. Miss. Mar. 19, 2008) (finding lack of reliance doomed express warranty claim under product liability act)	
Missouri		In re Bisphenol–A (BPA) Polycarbonate Plastic Prod. Liab. Litig., 687 F. Supp. 2d 897, 906 (W. D. Mo. 2009)

State	Reliance on Warranty	At Least Knowledge of Warranty
		("If one party is not aware of the statement, that party cannot claim the statement became a part of the parties' bargain."); <i>Interco Inc. v. Randustrial Corp.</i> , 533 S.W.2d 257, 262 (Mo. Ct. App. 1976) ("However, the catalogue, advertisement or brochure must have at least been read.")
Montana	Schlenz v. John Deere Co., 511 F. Supp. 224, 228 (D. Mont. 1981) ("Manufacturers such as defendants create express warranties if they make representations in advertising brochures that the purchaser relies on as part of the basis for the bargain.")	
Nebraska	Hillcrest Country Club v. N.D. Judds Co., 461 N.W.2d 55, 61 (Neb. 1990) ("[I]t is essential that the plaintiffs prove reliance upon the warranty.")	
New Hampshire		Kelleher v. Marvin Lumber & Cedar Co., 891 A.2d 477, 502 (N.H. 2006) ("To satisfy this requirement, a plaintiff claiming breach of express warranty based upon a representation in a catalog or brochure would have to prove, at a minimum, that he

State	Reliance on Warranty	At Least Knowledge of Warranty
		or she read, heard, saw or was otherwise aware of the representation in the catalog or brochure.")
New Mexico		Porcell v. Lincoln Wood Prod., Inc., 713 F. Supp. 2d 1305, 1318 (D.N.M. 2010) ("[R]epresentations in sales literature of which a purchaser was unaware cannot become part of the 'basis of the bargain' between the seller and the buyer.")
New York	Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 286 (E.D.N.Y. 2009) ("[A]ction for breach of express warranty requires reliance on that promise or representation.") (citing CBS Inc. v. Ziff–Davis Pub. Co., 553 N.E.2d 997, 1000–01 (N.Y. 1990))	
North Carolina		Maxwell v. Remington Arms Co., LLC, No. 10-918, 2014 WL 5808795, at *3 (M.D. N.C. Nov. 7, 2014) ("In determining whether a seller's affirmation or description becomes the 'basis of the bargain,' North Carolina courts look to certain factors, including 'whether the buyer knew of the seller's statements."") (quoting Pake

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State	Reliance on Warranty	At Least Knowledge of Warranty
		prove 'that she read, heard, saw or knew of the advertisement containing the affirmation of fact or promise.'") (quoting <i>Parkinson v. Guidant Corp.</i> , 315 F. Supp. 2d 741, 752 (W. D. Pa. 2004)
Rhode Island	Thomas v. Amway Corp., 488 A.2d 716, 720 (R.I. 1985) ("[P]laintiff has the burden of proving that the statements or representations made by the seller induced her to purchase that product and that she relied upon such statements or representations.").	
South Dakota		Schmaltz v. Nissen, 431 N.W.2d 657, 661 (S.D. 1988) ("Without having read or even known of this language, it is impossible to say this language was part of the basis of the bargain.").
Tennessee		Coffey v. Dowley Mfg., Inc., 187 F. Supp. 2d 958, 969 (M.D. Tenn. 2002), aff'd, 89 F. App'x 927 (6th Cir. 2003) ("In order to establish a prima facie claim for breach of express warranty, plaintiff must prove that the buyer was in fact induced by the

State	Reliance on Warranty	At Least Knowledge of Warranty
		seller's acts"); <i>Masters v. Rishton</i> , 863 S.W.2d 702, 706 (Tenn. Ct. App. 1992) " had never seen any advertisement for the helmet and had never heard any representations made about the safety of the helmet.")
Texas		McManus v. Fleetwood Enter., Inc., 320 F.3d 545, 550 (5th Cir. 2003) (applying Texas law) ("Although the precise level of reliance required under Texas law to recover for breach of express warranty is unclear, purchasers who did not read or consider the wardrobe door tag[] cannot be said to have relied on the allegedly misleading wardrobe tag to any extent.") (emphasis in original)
Utah	Mgmt. Comm. of Graystone Pines Homeowners Ass'n on Behalf of Owners of Condos. v. Graystone Pines, Inc., 652 P.2d 896, 900 (Utah 1982) ("It is generally true that reliance is necessary to establish a cause of action for express warranty.")	
Virginia		In re Hardieplank Fiber Cement Siding Litig., 284 F. Supp. 3d 918, 938 (D. Minn.

State	Reliance on Warranty	At Least Knowledge of Warranty
		2018) (applying Virginia law) ("If the buyer was never exposed to the alleged affirmation, the affirmation cannot be part of the basis of the bargain.")
Washington		Baughn v. Honda Motor Co., 727 P.2d 655, 669 (Wash. 1986) ("Although the UCC does not require a plaintiff to show reliance on the manufacturer's statement, he or she must at least be aware of such representations to recover for their breach.")
Wisconsin		Haley v. Kolbe & Kolbe Millwork Co., Inc., No. 14- 99, 2015 WL 3774496, at *17 (W.D. Wis. June 16, 2015) (Plaintiffs "have not come forward with evidence that plaintiffs saw the statements before purchasing the windows so that the statements can be considered part of the basis of the bargain.")
Wyoming	Atlas Const. Co., Inc. v. Aqua Drilling Co., 559 P.2d 39, 41 (Wyo. 1977) ("We have held in a water-well case that there can be no warranty unless there be a representation relied upon	

State	Reliance on Warranty	At Least Knowledge of Warranty
	which becomes the basis for the bargain.")	